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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/767,147   | 01/29/2004  | Andries Jan Smit     | VOB-34537US1        | 4624             |
| 116 7590 12/16/2008<br>PEARNE & GORDON LLP<br>1801 EAST 9TH STREET<br>SUITE 1200<br>CLEVELAND, OH 44114-3108 |             |                      |                     |                  |
| EXAMINER<br>BERHANU, ETSUB D   |             |                      |                     |                  |
| ART UNIT   |             | PAPER NUMBER         |                     |                  |
| 3768   |             |                      |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/767,147

**Applicant(s)**

SMIT ET AL.

**Examiner**

ETSUB D. BERHANU

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 32-40, 43-45, 47-58 and 60-72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 69, 71 and 72 is/are allowed.
- 6) ☒ Claim(s) 32-36, 38-40, 43-45, 47-50, 54-58, 60-68 and 70 is/are rejected.
- 7) ☒ Claim(s) 37 and 51-53 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### *Claim Rejections - 35 USC § 101*

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 32, 33, 38, 39, 43-45 and 62-65 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In addition to inquiry of whether a claimed method falls within a judicial exception, Supreme Court precedent (*Diamond vs. Diehr*, 450 U.S. 175, 184 (1981); *Parker vs. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876).) and recent Federal Circuit decisions, require that a claim drawn to a process must (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. If neither of these requirements is met by the claim, the method is not a patent eligible process under 35 U.S.C. 101 and is improperly directed to non-statutory subject matter. Thus, to qualify as a 35 U.S.C. 101 statutory process, the claim should positively recite the other statutory class (the thing or product) to which it is tied or positively recite the subject matter that is being transformed. As claims 32, 33, 38, 39, 43-45 and 62-65 are not tied to another statutory class, nor do they positively recite subject matter being transformed, they are improperly directed to non-statutory subject matter.

*Claim Rejections - 35 USC § 103*

4. Claims 32, 33, 38-40, 43-45, 47, 48, 54-57, 60 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kollias et al.'059 (previously cited).

Kollias et al.'059 discloses an instrument and method for measuring glucose concentrations by using fluorescence (see ABSTRACT). Figure 2 of Kollias et al.'059 discloses a light source 14 and a detector 18. Kollias et al.'059 discloses: an illumination area of about  $1\text{cm}^2$  or less (col. 5, lines 57-58); use of wavelengths in the range of 300-345 nm (col. 5, lines 27-32); a measuring window of detector 18 is held away from the surface of the skin since contact with the skin is made using a probe comprising optical fibers (see Figure 10A and col. 6, lines 51-53); an excitation wavelength of 420nm and an emission wavelength of 500 nm (col. 6, lines 46-67); reflected radiation being detected (see Figures 10A and 10B); multiple wavelengths in a normalizing section for determining glucose (col. 10, line 59 – col. 11, line 12), wherein normalizing one wavelength by using another wavelength is considered to be aggregating detected fractions of fluorescent radiation to an aggregated amount of detected electromagnetic radiation; ends of optical fibers (Figures 10A and 10B), wherein the ends include an irradiation and measuring window, and wherein the ends move relative to a measuring window of the detector which is located in the analyzing instrument, when the fiber is placed on the skin, the fiber and windows capable of being placed at an angle of 25-65 degrees relative to the skin surface; filters, lamps and laser diodes as light sources (col. 6, lines 25-28, col. 14, lines 1-10, col. 9, line 65 – col. 10, line 3); irradiation being changed when measuring a reflected and emission radiation (col. 13, line 66 – col. 14, line 47); an irradiation being performed in a pulse fashion (col. 9, line 6 – col. 10, line 12); different wavelengths being chosen using a wavelength selector (Figure 11, element 107 and col. 13, line 66 – col. 14, line 47); a support structure (col. 7, line 65 – col. 8, line 20) and control means (Figure 2, element 12) for controlling the excitation radiation of a light source, wherein the control means allows the apparatus to be capable of intermittently

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irradiating skin tissue and for separately detecting radiation from the skin tissue. Regarding the limitation in the claim that the size of the skin surface from which the measured fluorescent radiation is received is at least  $1\text{cm}^2$ , it is noted that while Kollias et al.'059 discloses the size of the skin surface irradiated, it fails to disclose the size of the skin surface from which measured fluorescent radiation is received. It would be obvious to one of ordinary skill in the art that in order to irradiate a skin surface of about  $1\text{cm}^2$  or less, the radiation delivery optical fiber shown in Figure 10A would need to be of a size large enough to irradiate such a skin surface size. As no details have been disclosed as to the size of the radiation pick-up optical fiber shown in Figure 10A, it would have been within the skill of the art to implement the same sized optical fiber for both the radiation delivery optical fiber and radiation pick-up optical fiber as Kollias et al.'059 fails to disclose details of the radiation pick-up optical fiber, but inherently discloses details of a radiation delivery optical fiber capable of irradiating a skin surface having a size of  $1\text{cm}^2$  and capable of being used as the radiation pick-up optical fiber. Further, it would have been well within the skill of the art to implement a radiation pick-up optical fiber capable of receiving measured fluorescent radiation from a skin surface having at least the same size, or a larger size, than the size of the skin surface irradiated as this would assure that a sufficient amount of measured fluorescent radiation is detected by the detector.

5. Claims 32, 35, 36, 47, 49, 50, 56-58 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al.'127 (previously cited).

Anderson et al.'127 discloses a method and apparatus for delivering ultraviolet radiation for the analysis of skin (see ABSTRACT), the method and apparatus comprising: effected skin covering an area of  $1\text{cm}^2$  (col. 3, lines 11-12); use of illuminators (Figure 1, elements 14 and 34) which deliver ultraviolet radiation and a detector (Figure 1, element 22); detecting reflected and fluorescent radiation (col. 3, line 65 – col. 4, line 4 and col. 17, lines 17-23); an array of detectors (col. 12, lines 14-16); a reference measurement made in the form of a spectrometer reflectance

ratio (Figure 4, element 138); a lamp as a light source (col. 9, lines 34-38); a spectrometer (Figure 1, element 49); and separate detectors for detecting reflected excitation radiation and fluorescent radiation (col. 12, lines 22-32). Figure 2 discloses that a measuring window (the CCD camera) is held at an angle of 25-65 degrees relative to the irradiated surface of the skin. Anderson et al.'127 discloses all the elements of the current invention except for the size of the fiber optic bundle (col. 16, lines 33-65) used to carry the diagnostic radiation to the skin and to receive the resulting diagnostic signal radiation from the skin. It would be obvious to one of ordinary skill in the art that in order to irradiate a skin surface of  $1\text{cm}^2$ , the fiber optic bundle would need to be of a size large enough to irradiate such a skin surface size. As the same fiber optic bundle is used to carry diagnostic radiation to and from the skin surface, the skin surface from which measured fluorescent radiation is received would also inherently be  $1\text{cm}^2$ .

6. Claims 34, 35, 62-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kollias et al.'059 further in view of Anderson et al.'127.

Kollias et al.'059 discloses all the elements of the current invention, as discussed in paragraph 4 above, except for the measured fluorescent radiation being received from a portion of the irradiated surface portion of the skin only, wherein the size of the skin surface from which the measured fluorescent radiation is received is at least  $1\text{cm}^2$  and the measured fluorescent radiation being received from an irradiated surface portion of the skin only. Kollias et al.'059 fails to disclose the size of the fiber optic cable that receives the measured fluorescent radiation, however, Kollias et al.'059 does disclose that the fiber optic cable that delivers radiation to the skin is of a size to irradiate a skin surface of about  $1\text{cm}^2$  or less. It would have been within the skill of the art to use the same sized fiber optic cable to receive the measured fluorescent radiation as the fiber optic cable used to deliver the radiation, since Kollias et al.'059 fails to disclose the size of the return fiber optic cable and Kollias et al.'059 teaches the use of a fiber optic cable (the radiation delivery fiber optic cable) capable of being used as the return fiber optic cable.

Anderson et al.'127 teaches that fiber optic bundles comprising separate radiation and delivery fibers are an alternate equivalent to a fiber optic bundle comprising a single fiber wherein the single fiber both delivers and receives diagnostic radiation data to and from the skin of a patient (col. 17, lines 55-67). It would have been within the skill of the art to substitute a fiber optic bundle comprising a single optic fiber to both deliver radiation and receive radiation from the same skin site, as taught by Anderson et al.'127, for the multiple fiber probe of Kollias et al.'059, since it has generally been held within the skill of the art to substitute alternate equivalent expedients.

#### ***Response to Arguments***

7. Applicant's arguments with respect to claims 32-36, 38-40, 43-45, 47-50, 54-58, 60-68 and 70 have been considered but are moot in view of the new ground(s) of rejection. Regarding Applicant's argument on pages 17-18 of the Remarks filed 09 September 2008, Examiner notes that the Anderson et al.'127 reference indicates that single optical fibers are capable of being used as an alternate equivalent to optical systems comprising a separate sending and receiving fiber. In substituting the single optical fiber of Anderson et al.'127 for the dual optical fiber system of Kollias et al.'059, the measured fluorescent radiation is received from a portion of the irradiated skin surface portion only. Anderson et al.'127 was not considered to look for an improvement of what was disclosed by Kollias et al.'059, but rather as a means to substitute two alternate equivalents. For this reason, the rejection of claims 62-65 are upheld.

#### ***Allowable Subject Matter***

8. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art teaches or suggests, either alone or in combination, a method or apparatus for determining a signal which represents a determined advanced glycation/glycosylation end

product content wherein either: an irradiated skin tissue area is located behind an opening in a supporting structure held against the skin of a patient, wherein the supporting structure also supports a measuring window or a measuring window is situated at an angle of 25-65 degrees relative a plane defined by a supporting structure held against the skin of a patient, wherein the measuring window is located to receive radiation emitted from the skin in a direction at an angle to the direction of excitation radiation, in combination with the other claimed steps or elements.

9. Claims 37 and 51-53 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Claims 69, 71 and 72 are allowed.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ETSUB D. BERHANU whose telephone number is (571)272-6563. The examiner can normally be reached on Monday - Friday (7:00 - 3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/  
Primary Examiner, Art Unit 3768

EDB